

Legislative

Cigarette Labeling and Advertising Act

Fire Safe Cigarette Act

Federal Aviation Act

Statutes with Tobacco Exemption

Pending Federal Legislation

- **Tobacco and Nicotine Health and Safety Act**
- **Tobacco Protection, Education and Health Protection Act**

State Legislation

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SEC
FAA
-
T&N
-
Advertising
FTC
-
State
-
Federal
FDA

Regulatory

PM 2000

The cigarette for the future

Feels, draws and tastes like other cigarettes

Each PM 2000 provides 8-10 puffs - like other cigarettes

In addition, PM 2000:

- **Produces absolutely no sidestream smoke**
- **Is fireproof**
- **Is odor free**
- **Creates no ashes and requires no ashtray**
- **Does not burn between puffs and the smoker can wait hours (or even longer) between puffs with no effect on taste**
- **Comes in packs of 20 that fit comfortably in pocket or purse**
- **PM 2000's stylish safety lighter fits comfortably in a smoker's hand**
 - **One charge of the lighter's batteries lasts all day**
 - **Batteries can be recharged in 30 minutes or less**

Just place a PM 2000 into the safety lighter and smoke whenever you choose

- **A smoker can wait hours between puffs with no effect on taste**
- **Between puffs, the lighter and PM 2000 can be held in the hand or placed on any surface**
- **No ashtray is needed**

The lighter's battery recharger is attractive, compact, light weight and portable

- **The home/office model is powered by 120V AC**
- **The car model conveniently plugs into a car's cigarette lighter**

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Major Action Areas to Protect and Announce Product Launch

Key Concerns:

I) Preintroduction leak to media

II) Introduction

- Antis petition FDA/FTC to stop product intro and/or ads
- Antis petition state/local health authorities to stop intro
- Legislative actions (bills/hearings)
- Protests at retail outlets
- Media strategy: print and electronic

Action	PM Response
Preintro leak to media	<p>[official response]</p> <p>"We are always examining and testing many product innovations and variations, both our own and our competitors'. Until we decide to bring one to market, we have no comment."</p> <p>[on background we would argue strongly that anything written on it would be premature and probably wrong. Also, our tests of the product would coincide with tests of premiere so we could say we were really monitoring RJR's product changes.]</p>

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Petition for FDA regulation	<ol style="list-style-type: none"> 1. Develop legal arguments against FDA jurisdiction/action. 2. Prepare appropriate team to meet with FDA officials. 3. Create/activate coalition against FDA regulation of tobacco products (N.B.: nature of product may move drug companies who sell nicotine products to support FD action.)
Petition for FTC action on product and/or advertising	<ol style="list-style-type: none"> 1. Develop legal arguments against FTC action 2. Prepare appropriate team to meet with FTC officials 3. Activate freedom to advertise coalition
Petition to state/local health authorities to stop product or advertising	<ol style="list-style-type: none"> 1. Develop legal arguments against such state/legal action. 2021366857 2. Identify and prepare team in each state to meet with regulatory and executive branch officials. 3. Prepare general anti-regulation alliance in each state including private sector and legislators.

Legislative hearings on bills	<ol style="list-style-type: none"> 1. Develop arguments on product issues. 2. Activate PM-specific coalition and allies on tobacco issues.
Protests at retail outlets	<ol style="list-style-type: none"> 1. Provide onsite media assistance to affected retailer(s). 2. Prepare examples of other product protests to show that stores would be empty if all protest groups had their way.
Media strategy for introduction	<ol style="list-style-type: none"> 1. Initiate story and let antis respond so we drive the lead in all stories. 2. Prepare detailed press release, product samples and advertising copy for business media. 2021366858 3. Develop and release video tape of product function and design and have spokesperson trained and ready for electronic media. 4. Press release and briefing should coincide with sales force briefing for trade sell in.

TABLE MEETING AGENDA
26th Floor Presentation Room
December 11, 1992
2:00 - 4:00 p.m.

- | | | |
|------|--|----------------------|
| I. | Introduction of Presentation and Product | S. Parrish |
| II. | Situation Analysis | C. Levy |
| III. | Business Implications and Objectives | J. Nelson |
| IV. | Strategies and Plans | |
| | A. Development and Manufacturing | C. Lilly, J. Myracle |
| | B. Marketing | R. Mikulay |
| | C. Finance | H. Long |
| V. | Benchmarks and Decision Points | B. Reuter |
| VI. | Summary | S. Parrish |

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TABLE MEETING AGENDA
Conference Room 22A
January 28, 1993
3:30 - 5:30 p.m.

- | | | |
|------|--------------------------------------|----------------------------|
| I. | Introduction | Steve Parrish |
| II. | Situation Analysis | Carolyn Levy |
| III. | Business Implications and Objectives | Jack Nelson |
| IV. | Strategies and Plans | |
| | A. Development and Manufacturing | Cliff Lilly
Jim Myracle |
| | B. Marketing | Bob Mikulay |
| | C. Finance | Henry Long |
| V. | Benchmarks and Decision Points | Barbara Reuter |
| VI. | Summary | Steve Parrish |

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BETA

Feel, draw and taste like other cigarettes

Provide 8-10 puffs - like other cigarettes

Produce absolutely no sidestream smoke

Firesafe

Odor-free

Create no ashes and require no ashtray

Will not burn between puffs and the smoker can wait hours
(or even longer) between puffs with no effect on taste.

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- Admission of causation
- Assurance of safety
- Safer alternative design
- Environmental Tobacco Smoke

Product Liability Issues

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2. No adverse legislation or regulation is enacted

1. We do not run a foul of existing legislative or regulatory requirements or prohibitions

Our strategy is to ensure that:

~~Legislative and Regulatory Issues~~

To Be Successful

- ~~PM must find partner to integrate and assemble~~
- Partner would package and ship
- Partner would supply new technology awareness
 - Motorola
 - Sony
 - Sanyo
 - Siemens
 - Phillips
 - Medium Size Companies (A.D. Little)

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Whether a product is a "drug" or a device" subject to FDA regulation depends on the use intended by the manufacturer of the product.

1. **"Drugs" are products intended for use in the prevention or mitigation of disease and intended to affect the structure or any function of the body.**
2. **"Devices" are products intended for use in the prevention or mitigation of disease and intended to affect the structure or any function of the body, when the products do not achieve their primary intended purposes through chemical action in the body and do not depend on being metabolized to achieve those purposes.**

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1. promotional statements, both written or oral, of the manufacturer, most classically from product labelling and advertising;
2. statements in patent applications;
3. statements in required SEC filings and similar documents; and
4. purely internal company documents describing the product, the product's competition, plans for marketing the product, etc.

The intended use of a product may be determined from:

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Consequences of FDA Regulation

1. If a drug, requires new drug application.
2. If a device, requires premanufacture application.
3. If either, FDA regulation entails safety and efficacy testing.

Testimony of Dr. Jeffrey Harris on behalf of Plaintiff in CIPOLLONE

- Cancer causing PAH's and other compounds are formed in a "very hot zone, right behind the burning tip" of the cigarette.
- To improve the product it is necessary to "clean up the chemical reaction" in the cigarette and make it burn more efficiently.
- The Palladium cigarette was safer because it had reduced biological activity as measured by animal tests - it substantially reduced the risk of lung cancer.
- There was no legitimate reason not to market the product.
- It would have been "prudent" for Liggett to market the product.

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